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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,684	11/20/2001	David Samuel Cohen	BT12 00102601 (USP)US	9719

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EXAMINER

SIEFKE, SAMUEL P

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/989,684	Applicant(s) COHEN ET AL.	
	Examiner Samuel P. Siefke	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9,12,15-31,77,78 and 91-94 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9,12,15-31,77,78 and 91-94 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/18/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9, 12, 15-31, 77-78 and 91-94 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-57 of copending Application No. 09/997,895. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims comprise a separation chamber. While 09/997,895 does not claim an entry port, it would have been obvious that the sample has to be applied to the optical disk in some manner, and it would have been obvious to provide such an entry port to provide convenient access to the disk for application of a sample.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims **9, 12, 25-31, 77-78, 91-94** are rejected under 35 U.S.C. 102(e) as being anticipated by Virtanen (USPN 6,030,581).

Virtanen discloses a laboratory in a disk that comprises: an optical disk, adapted to be read by an optical reader, comprising a first sector having a self-contained assay means for localizing an analyte suspected of being in a sample. The disk comprises a sample entry chamber (14), and a separation zone (17) downstream of the entry chamber (fig. 2A). The separation zone specifically separates the analyte from the sample. Filters are included as part of the sample inlet, and are formed from porous plastic, glass, cellulose, etc. These materials may be in the shape of rods or similar shapes depending on the particular use to which they are being applied (col. 7, lines 35-43). Further the filters may be used to removed large particles, such as cells, dust, etc. from the soluble sample. The filters may be formed from porous plastic, glass, cross-linked cotton or cellulose, etc (col. 7, lines 36-43). The filters above anticipate the separation structure of the instant application. It is noted that these may be in the

sample inlet, but are located downstream from the entry chamber (col. 7, lines 54-65). The optical disk includes a substrate including tracking grooves (col. 5, lines 21-23) and a reflective layer formed on the substrate (col. 7, lines 9-35) so that an incident beam can track along the groove (col. 4, lines 17-61) where a reader detects information that identifies the particular analyte (col. 5, lines 35-53). Virtanen further discloses tracking grooves as capillary ducts and fluid storage and retention compartments that are machined into the optical disk or formed by chemical means or injection molding operations. The depths are about 1-2000 um preferably about 10-800 um and they may have any shape possible (col. 6, lines 55-60). With respect to quantifying the agglutinants in the entry chamber by determining an amount of the tracking groove that is at least partly covered by particle agglutinants, Virtanen discloses the analytes bind to a predetermined location on the disk if it is present in the sample and the presence of the analyte is detected by the reader from information that identifies the particular analyte with the location at which it is bound (col.5, lines 44-47). A multiplicity of assay sectors 21,22,23 as shown in figure 3 may be provided, each sector connected to an individual sample inlet port 24, 25, 26 respectively. The liquid flow during the assay may be monitored by using a reflective element. The reflective element utilizes the laser that is in the CD or DVD reader and the fact that even when the liquid is transparent its reflective index is significantly different from that of air. The optical disk further comprises a collection zone (20) downstream of the separation zone (fig. 2A). The optical disc includes a mixing chamber (15) where buffers can be mixed with the sample (col. 5, lines 25-35). The optical disc contains a center where the sample is

added and upon rotation the sample migrates toward the outside of the disc in the order of sample entry, separation zone, collection zone (fig. 2A, 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims **15-24** and are rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen (USPN 6,030,581).

Virtanen discloses a laboratory in a disk that comprises: an optical disk, adapted to be read by an optical reader, comprising a first sector having a self-contained assay means for localizing an analyte suspected of being in a sample.

Virtanen does not teach specifically that the separation zone includes series of slits formed in the substrate to allow small particles to pass through, along with how these structures are described (rib, increasing and decreasing size of the slits). It would

have been obvious to modify Virtanen to include such a separation zone as described above because it is known in the art of particle separation that creating slits or ribs that decrease in size allows for larger particles to be separated from the sample and allowing smaller particles to continue on through the separation zone. With respect to the optical disc of Virtanen teaching a material holding zone that holds freeze-dried bioactive agent material, Virtanen teaches a sample prep area (fig. 1A) that includes agents that prepare the sample for separation (col. 12, lines 45-67). It would have been obvious to one having an ordinary skill in the art to modify Virtanen to include freeze-dried bioactive agent material in the sample preparation zone because in order to provide a disc which is ready-for-used and has a stable, extended shelf life.

Response to Arguments

Applicant's arguments filed 2/04/05 have been fully considered but they are not persuasive. Applicant argues, "Virtanen does not teach or suggest use of a tracking groove in quantifying partial agglutinants." Tracking grooves can be in the broadest interpretation, grooves in a substrate that allow a liquid to move where they can be tracked. Virtanen does just this by disclosing a path (groove) by which an analyte can move through and bind to a predetermined location on the disk and if it is present in the sample, the presence of the analyte is detected by the reader from information that identifies the particular analyte with the location at which it is bound (col.5, lines 44-47).

The applicant argues, "Virtanen does not teach or suggest "a separation structure... comprising a plurality of structures that define gaps therebetween, *the distance between the gaps being less than or equal to a width of the particle agglutinants.*" The fundamental principles of a filter are that it contain gaps or spaces that are less than or equal to a width of a particle of interest, this is how something is filtered out. If the one wants larger objects to be filtered out then the gaps must be equal to the width of the particle of interest so that larger particles are trapped or stopped by the small gaps. Virtanen anticipates this limitation.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P. Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sam P. Siefke



May 2, 2005


Jill Warden
Supervisory Patent Examiner
Technology Center 1700